



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 24, 2015

Mr. Steven R. Spaulding
Senior Director, Regulatory Affairs
Farnam Companies, Inc.
1501 E. Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: PRIA Label Amendment – Addition of Swine Feed-Through New Use
Product Name: RMI-2011-B
EPA Registration Number: 270-379
Application Date: April 1, 2014
Decision Number: 489559

Dear Mr. Spaulding:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(C)(7)(B), and is subject to the following conditions:

1. You must submit and/or cite all data required for registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Diflubenzuron GDCI-108201-1286

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
http://www.epa.gov/oppsrrd1/contacts_prd.htm

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18

months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or Rodia.Carmen@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

*Enclosures: Label Stamped "Accepted," dated November 24, 2015
EFED Risk Assessment, dated September 30, 2015
HED Risk Assessment, dated October 27, 2015
Waiver Request to Register a Diflubenzuron Feed-Through Product for Swine Fly Control, dated October 27, 2015*

[] & () denote optional language

RMI-2011-B

Alternate brand name: ClariFly® Larvicide Concentrate 8%

AN INSECT GROWTH REGULATING PRODUCT FOR USE IN [(CATTLE), (EQUINE) AND (SWINE)] FEEDTHROUGH PRODUCTS FOR CONTROL OF FLIES DEVELOPING IN MANURE

(Daily) feed concentrate for cattle (horses) (swine) containing [(diflubenzuron)(brand name)] Insect Growth Regulator (IGR) for continuous feeding during the fly season [(Fly larvicide)(fly control)] for [(cattle)(horses)(and)(swine)] Controls flies [(developing) (growing)] in manure [of treated (cattle)(horses)(and)(swine)] [(Stops)(Prevents the)] development of (House fly) (Stable fly) (Face fly) (Horn fly) (and) (manure breeding fly) larvae in manure [(of)(from)] treated [(cattle)(horses)(and)(swine)] [(Stops)(Prevents the)] [(development)(emergence)] of (House flies) (Stable flies) (Face flies) (and) (Horn flies) in the manure [(of)(from)] treated (cattle) (lactating and non lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves)(and horses). [(Stops)(Prevents the)] [(development)(emergence)] of manure breeding flies in the (manure)(waste) of treated swine (including nursery, grow-finish and breeding stock). Contains [(diflubenzuron)(brand name)(Insect Growth Regulator)(IGR)(chitin synthesis inhibitor)] Breaks the [(fly)(flies')] life cycle Prevents the [(formation)(synthesis)] of (chitin in) fly larvae's exoskeletons (when they molt)(resulting in their death) (Can be used as) part of [(an integrated)(a total)(a complete)] (fly control)(pest management) program Insect Growth Regulator (IGR) for continuous feeding during the fly season

ACTIVE INGREDIENT:

Diflubenzuron [CAS# 35367-38-5]..... 8%

OTHER INGREDIENTS: 92%

Total..... 100%

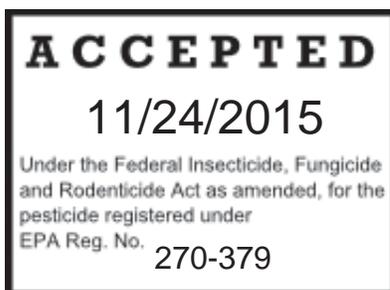
Contains 1.28 ounces (36.32 grams) of diflubenzuron per pound.

KEEP OUT OF REACH OF CHILDREN CAUTION

See [side][back] panel(s) for additional Precautionary Statements

Net Weight: _____ lbs

EPA Reg. No. 270-379
EPA Est. No.



Lot Number:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If on Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, call 1-800-347-8272, 24 hours per day, 7 days per week.	

PERSONAL PROTECTIVE EQUIPMENT

Mixers and other handlers must wear long-sleeved shirt and pants, shoes plus socks and chemical resistant gloves. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[(ClariFly® Larvicide Concentrate 8%)(This product)] [(prevents)(inhibits)(controls)] the [(development of fly larvae in)(fly emergence from)] the manure of treated [(cattle)(horses)(and)(swine)]. When fed to [(cattle)(horses)(and)(swine)] according to label directions, [(ClariFly® Larvicide Concentrate 8%)(This product)(Diflubenzuron)] prevents the [(development)(emergence)] of [(horn flies), (face flies), (house flies) and (stable flies) (manure breeding flies)] [(in)(from)] the manure of treated [(cattle)(horses)(and)(swine)]. Start feeding [(ClariFly® Larvicide Concentrate 8%)(This product)] early in the spring before flies begin to appear and continue feeding throughout the summer and into the fall until cold weather restricts fly activity.

[(ClariFly® Larvicide Concentrate 8%)(This product)(Diflubenzuron)] prevents the [(development) (emergence)] of [(horn flies), (face flies), (house flies) and (stable flies) (manure breeding flies)] [(in)(from)] the manure of [treated (cattle)(horses) (and) (swine)], but is not effective against existing adult flies. When starting a feeding program during the fly season, it is desirable to use other control measures to reduce the population of existing adult flies.

In some cases, supplemental fly control measures may be needed in and around [(cattle)(horse)(and)(swine)] [(lots)(buildings)(stalls)(barns)(paddocks) (facilities)(sheds)(houses)] to control adult house flies and stable flies, which can breed not only in [(cattle)(horse) (and) (swine)] manure, but in decaying vegetable matter or silage on the premises. In order to achieve optimum fly control, use [(ClariFly® Larvicide Concentrate 8%)(this product)(Diflubenzuron)] in conjunction with other good management and sanitation practices.

The dosage of [(ClariFly® Larvicide Concentrate 8%)(this product)] is proportional to the animal's body weight and must be offered daily throughout the entire fly season. The following table [(gives dosage information)(provides the feeding rate)] for all approved species.

Species	Daily Feeding Rate of DFB AI	
	mg/kg	mg/cwt
Cattle - [(ClariFly® Larvicide Concentrate 8%)(This product)] may be fed to beef and dairy cattle, including breeding cattle, lactating dairy cattle, growing and finishing cattle and calves, either in dry lot or on pasture up to slaughter and to lactating dairy cows without withholding milk from market during or after treatment.	0.10	4.55
Horses - [(ClariFly® Larvicide Concentrate 8%)(This product)] may be fed to horses including ponies, burros, and donkeys. This product is not approved for use in pregnant mares.	0.15	6.82
Swine - [(ClariFly® Larvicide Concentrate 8%)(This product)] may be fed to swine including nursery, grow-finish, and breeding stock with no withdrawal period. Use the higher inclusion rate for lighter weight pigs.	0.20 - 0.30	9.10 – 13.64

[(ClariFly® Larvicide Concentrate 8%)(This product)] is a specially formulated granular material for use in [(cattle)(horse)(and)(swine)] feeds. It is approved for use in [(supplements)(complete feeds)(concentrates)(premixes)(hand feeds)(mineral supplements)(blocks)(tubs)]. It may also be used in [(liquid feeds)(dry milk replacer)] when suspension agents are used to maximize the positional stability of the other feed ingredients.

(Cattle) Feed Mixing Directions - 0.10 mg/kg/day

The following formula can be used when mixing cattle rations, including complete feeds, liquid feeds, supplements, premixes, supplements for hand feeding and mineral mixes.

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.25 = \frac{\text{lbs of ClariFly Larvicide Concentrate 8\% per Ton of product being manufactured}}{\text{Ton of product being manufactured}}$$

Feed Mixing Directions for Calves Weighing Between 50 and 200 Pounds

Use the following table when formulating (calf starters) and (milk replacers) to be fed to calves weighing between 50 and 200 pounds:

CALF WEIGHT	FEED INTAKE lbs/head/day	INCLUSION RATE	
		Lbs of (brand name)/ton	G of Diflubenzuron/ton
50 – 99 lbs	1.0 – 1.4	0.250	9.1
100 – 150 lbs	1.0 – 1.4	0.375	13.6
100 – 170 lbs	1.5 – 1.7	0.300	10.9
100 – 200 lbs	≥ 1.8	0.250	9.1

(Horse) Feed Mixing Directions - 0.15 mg/kg/day

The following formula can be used when mixing horse rations, including complete feeds, tubs and blocks.

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.375 = \frac{\text{lbs of ClariFly Larvicide Concentrate 8\% per Ton of product being manufactured}}{\text{Ton of product being manufactured}}$$

(Swine) Feed Mixing Directions - 0.20 mg/kg/day – 0.30 mg/kg/day

The following formula can be used when mixing swine rations.
Use the higher inclusion rate for lighter weight pigs.

For a dosage of 0.20 mg/kg/day:

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.5 = \frac{\text{lbs of ClariFly Larvicide Concentrate 8\% per Ton of product being manufactured}}{\text{Ton of product being manufactured}}$$

For a dosage of 0.30 mg/kg/day:

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.75 = \frac{\text{lbs of ClariFly Larvicide Concentrate 8\% per Ton of product being manufactured}}{\text{Ton of product being manufactured}}$$

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this pesticide may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into mixing equipment. Offer for recycling if available, then dispose of empty bag in a sanitary landfill or by other procedures approved by State and local authorities.

CONDITIONS OF WARRANTY AND LIMITATION OF LIABILITY

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The Directions for Use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Central Garden & Pet Company. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Central Garden & Pet Company makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Central Garden & Pet Company is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Central Garden & Pet Company disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Central Garden & Pet Company's election, the replacement of product.

For information or in case of emergency, contact 1-800-xxx-xxxx.

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